DATES

Application Rec'd _____
Human Subjects Rec'd _____
Reviewed & Approved _____
Added to Req. List _____
Guidelines Sent _____

Networked to/from: PED ____
CWRU ____
UPENN ____
OSU ____
UAB ____

APPLICATION: COOPERATIVE HUMAN TISSUE NETWORK

I. DIRECTIONS

The information requested in these forms is necessary in order to correctly document your request for tissue and other services and to ensure that the CHTN operates within the guidelines of the National Cancer Institute. When submitting a written request for services:

A. Please print neatly or type.

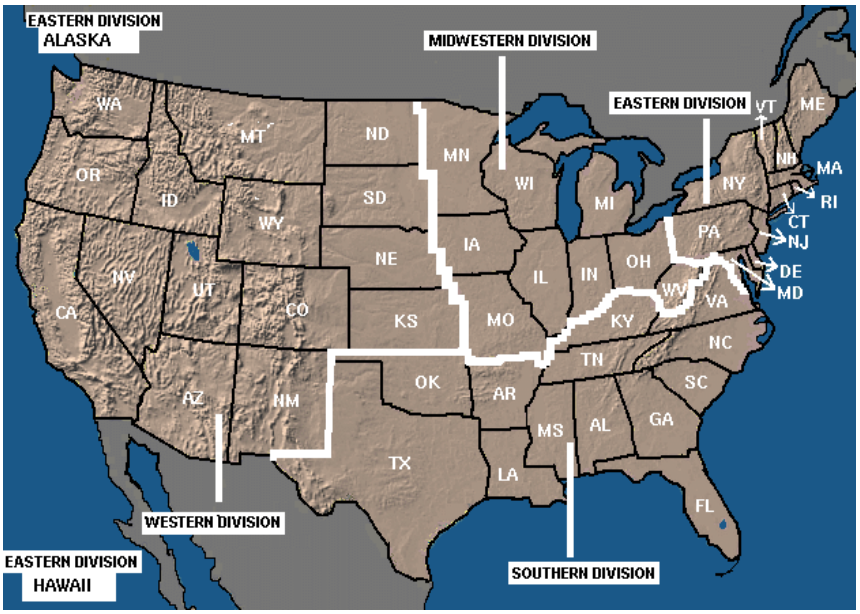
B. Please be specific about your requirements for handling tissue specimens from the time the specimen is collected until it is delivered to your lab (i.e., need for sterility, transport media, refrigeration status, etc.).

C. Patient identity is confidential. Specimens will be coded and delivered at a processing fee of $20/specimen plus shipping costs. Additional charges may be assessed for special preparation.

D. **Investigators must have human use approval to receive tissue from the CHTN. Either full or expedited approval can be obtained from your Institutional Review Board (Human Use Committee). <u>A COPY OF THE HUMAN SUBJECTS APPROVAL SHOULD BE ATTACHED TO THIS FORM</u>.** An annual human subjects review is required and must be forwarded to the CHTN in order to maintain your eligibility to receive tissue.

E. For pediatric tissue (available nationwide) please complete this application and the supplemental pediatric application and mail directly to Children's Hospital at the address shown below.

F. For additional information call the Division for your state (see map below). Send completed forms to the appropriate Division as shown below.



EASTERN DIVISION
Kelly Feil
University of Pennsylvania Med. Center
Department of Pathology and Lab. Med.
3400 Spruce Street
Founders Pavilion, 6th Floor
Philadelphia, PA 19104-4283
215-662-4570
215-614-6554 (FAX)
E-mail chtneast@mail.med.upenn.edu

MIDWESTERN DIVISION
Carolyn Cordial
The Ohio State University
Tissue Procurement, N-305 Doan Hall
410 W. 10th Avenue
Columbus, OH 43210
614-293-5493
614-293-5851 (FAX)
E-mail cordial-1@medctr.osu.edu

PEDIATRIC DIVISION
Nancy Sachs
Children's Hospital
700 Children's Drive
Room J058
Columbus, OH 43205
614-722-2890
614-722-2897 (FAX)
E-mail nsachs@chi.osu.edu

SOUTHERN DIVISION
Katherine Sexton
Tissue Procurement, ZRB 449
University of Alabama at Birmingham
703 South 19th Street
Birmingham, AL 35294-0007
205-934-6071
205-934-0816 (FAX)
E-mail sexton@tp.path.uab.edu

WESTERN DIVISION
Diane Zokle
Institute of Pathology
Tissue Procurement
Case Western Reserve University
Cleveland, OH 44106
216-844-8538
216-844-8522 (FAX)
E-mail dmz2@po.cwru.edu

II. INVESTIGATOR DATA

A. Principal Investigator:_____
Last name First Name Middle Initial Degree

Investigator's Title:_____

Primary Mailing Address (Street/Bldg./Room#):_____

_____

Department:_____

Institution:_____

City:_____ State:_____ Zip:_____

Phone (Day):_____ (Nights/Weekends):_____

FAX Number at which you may be notified:_____e-mail_____

Contact Person:_____ Lab/Phone:_____e-mail_____

B. Shipping Address (if different from above):

Department:_____

Street/Bldg./Room#:_____

City:_____ State:_____ Zip:_____

C. Billing Information: Is a purchase order required for shipment of specimens to your institution? Y __ N__ If so, please list name of contact for P.O.:

Name:_____Phone:_____

Currently invoices are included with the tissue shipment to the shipping address listed in section B. If you would like the original invoice to be mailed to another location (eg. Your billing department), please enter that address below. A copy of the invoice will also be included with your shipment.

Billing Address (if different from the shipping address):

Department:_____

Street/Bldg./Room#:_____

City:_____ State:_____ Zip:_____

(Shipping charges will be billed unless you provide a Federal Express number.)

Federal Express Number_____

III. Funding Information

Tissues will be provided to investigators on a rotating basis in the following priority order:
1. Peer reviewed funded investigators (including Federal and National laboratories)
2. New investigators and academic investigators developing new research projects.
3. Other investigators

A. To help determine your priority, Please include your major research grant. Institutional and other funding sources may be listed. If you are currently unfunded, please indicate below:

Funding Source	Period of Support

B. Please provide the title and a short research summary of the proposed research on the tissues you are requesting from the CHTN (use separate page):

IV. SERVICES REQUESTED (Please copy this page as needed for multiple requests.)

A. Human Tissue Specimen Criteria

1. Anatomic Site or Tissue Type: _____

_____Malignant; _____Benign; _____Normal; _____Diseased; _____Other: _____

If malignant is selected, please specify: Any malignant _____ OR specify type of malignancy:_____

If malignant is selected, _____ Primary and/or mets _____ Primary only

2. Is matched normal tissue from the same patient required? ___Yes; __No; __If available
3. Will you accept tissue from patients previously treated with: ___Radiation; ___ Chemotherapy
4. Must specimen be sterile? _____Yes; _____No; _____As clean as possible
5. Gender: _____ Male _____ Female _____ Either
6. Tissue Source:

___Surgical: Must be frozen within ___hrs of sx OR ___time constraint not applicable

____Autopsy: Must be collected within _____ hours after death

7. Patient Limitations (i.e., age, race, or other limiting characteristics): _____

_____

8. Amount of tissue required (minimum to maximum size or dimension): _____
9. Frequency tissue is needed:_____
10. Total number of specimens needed:_____
11. Requested starting date to receive tissue:_____

B. Preparation and Preservation of Specimens (please mark only those that apply)

____ **Fresh.** Indicate media requirements:

_____ Transport Media; _____ Saline; _____ Dry

(if preference for transport media, e.g. RPMI, L-15, DMEM, please indicate): _____

Wrap in Gauze? _____Yes _____ No

Add supplements:

___Antibiotics (indicate type & amount) _____

___Fetal Calf Serum (indicate percentage) _____

___Fungizone (indicate amount) _____

Shipping Requirements (wet ice, room temp, etc.) _____

____ **Frozen.** Indicate freezing requirements (fresh-frozen, OCT, etc.):_____

____ **Fixed**. Indicate fixative requirements (10% BNF, etc.):_____

Will you accept Saturday deliveries, if notified? _____Yes; _____No _____Sometimes if notified

C. Specimen Information Required: (Anatomic site of tissue, provisional diagnosis, final diagnosis, quality control diagnosis and patient age, sex and race (if available) will be provided for all specimens.) Please list any additional information requirements **and the reason for your request**:

_____

_____

_____

_____

(NOTE: please notify your division coordinator ASAP if your needs change).

AGREEMENT

The recipient hereby agrees: that the tissues to be provided by the Cooperative Human Tissue Network will be used only for the research purposes specified in this application; that no attempt will be made to learn the identity or other information about the subjects providing tissue; and that tissues and their products shall not be sold (or distributed free of charge) to third parties, nor used to produce commercial products (including the production of cells or cell products for sale).

We understand that while the CHTN attempts to avoid supplying tissues contaminated with highly infectious agents such as hepatitis and HIV, all tissues should be handled as if potentially infectious. The recipient acknowledges that he/she is aware of and follows OSHA regulations for handling human specimens and will instruct their staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

Tissues are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. The CHTN accepts no responsibility for any injury (including death), damages or loss that may arise either directly or indirectly from their use.

The recipient hereby agrees to acknowledge the contributions of the Cooperative Human Tissue Network in all publications resulting from the use of these tissues. Recommended wording to the methods or acknowledgment section is as follows: *Tissue samples were provided by the Cooperative Human Tissue Network which is funded by the National Cancer Institute. Other investigators may have received specimens from the same subjects.*

FOR STATE INSTITUTIONS: The recipient institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise solely from the receipt, handling, storage and use of tissues received from the CHTN to the extent permitted under the laws of this State. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

FOR U.S. GOVERNMENT AGENCIES: On behalf of the United States Government, we assume all risks and responsibilities in connection with the receipt, handling, storage and use of tissues received from the Cooperative Human Tissue Network. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

FOR ALL OTHER INSTITUTIONS: The recipient institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of tissues. It further agrees to indemnify and hold harmless the Cooperative Human Tissue Network and the United States Government from any claims, costs, damages or expenses resulting from the use of the tissues provided by the CHTN. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT

Typed Name of Recipient	**Agency**	**Typed Name of Official Authorized to Sign for the Agency**
Signature of Recipient **Date**	**Division or Department**	**Authorized Signature** **Date**

UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTED ABOVE, THE COOPERATIVE HUMAN TISSUE NETWORK WILL CONSIDER THIS REQUEST AND ALL FUTURE REQUESTS FOR TISSUE. Specific questions about your application should be directed to your regional coordinator. Other questions may be directed to the NCI Program Director, Dr. Roger Aamodt at 301 496-1591